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09/498,554	02/04/2000	James L. Winkler	03848-85586	8957

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BANNER & WITCOFF LTD.,
ATTORNEYS FOR AFFYMETRIX
1001 G STREET, N.W.
ELEVENTH FLOOR
WASHINGTON, DC 20001-4597

EXAMINER

LUDLOW, JAN M

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 05/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/498,554

Applicant(s)

WINKLER ET AL.

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2002 and 28 August 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-207 is/are pending in the application.
- 4a) Of the above claim(s) 148-207 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-147 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 May 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 12 April 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. This is a supplemental action, replacing the action mailed December 6, 2002.
2. Claims 166-207 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 19.
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Note that the instant claims have an effective filing date of 11/20/1992.

7. Claims 48-91, 93-116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pirrung (WO/90/15070) in view of Southern (WO 89/10977) and Hayes (4877745) and Prats (4937593).

Pirrung et al teach a method for forming arrays of biological polymers by coating a substrate with a protected linker, using a mask to deprotect in desired areas, adding an optionally protected monomer, reacting with the linker and repeating the steps to form an array (See, e.g., p. 4-7; pages 14-16, page 18 and page 28).

Pirrung fails to teach depositing by a dispenser as claimed.

Southern teaches a method similar to that of Pirrung. An ink jet printer may be used to deposit monomers (p. 11).

Hayes teaches an ink jet printer for printing reagents. Droplets of 100 picoliters to 1 microliter are produced. Multiple dispensers 400 and movement between the print head(s) and substrate are used.

Hayes fails to teach positioning of the print head.

Prats teaches precise positioning of a print head in X, Y and Z directions to enhance printing (col. 1, lines 38-55) using an optical positioning system.

It would have been obvious to provide the monomers in the invention of Pirrung using an inkjet print with plural heads and relative motion means in order to provide the monomers by known means as taught by Pirrung on page 4, the known means being

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suitably an inkjet printer as taught by Southern and Hayes. It would have been obvious to provide the dispenser spaced from the surface in order to permit drop formation and to provide means to move the dispenser relative to the substrate in order to provide art recognized equivalent to moving the substrate relative to the dispenser as taught by Prats. It would have been obvious to provide known alternative position sensing means in the device as modified by Prats as was known in the art.

8. Claims 48, 82, 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pirrung in view of Sanz and Meltzer.

The teachings of Pirrung are given above.

Pirrung fails to teach a pipet or plurality of pipets.

Sanz teaches a micropipet for dispensing 1 nl of biological fluids (col. 1, lines 5-12).

Meltzer teaches a positioning device for pipets for pipetting small volumes. The pipets are precisely located in the X-Y-Z dimensions (col. 1, lines 50-60) by a computer using optical, magnetic or other position detectors (col. 8, lines 1-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the pipet of Sanz with the positioning device of Meltzer in the method of Pirrung in order to provide the monomers by known means as taught by Pirrung on page 4, the known means being dispenser(s) of small volumes precisely into arrays as taught by Sanz and Meltzer.

9. Claims 48-91, 93-118, 120-146 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deeg (5378638) in view of Pirrung and Prats.

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10. Deeg teaches formation of a reagent array using an ink jet printer. Droplets of 20-2000 picoliters are used to make spots of 500 square μm to 0.2 square mm and may be bound to the substrate surface (col. 3, lines 27-41). Multiple dispensers may be used (col. 5, lines 35-36). The exemplary reagents are antigens, antibodies and labels used in immunoassay, but other specific binding assays can be used (col. 1, lines 35-43).

Deeg fails to teach nucleic acids or spacing the print head.

Pirrung teaches that nucleic acids may be used in specific binding assays as an alternative to immunoassay (bridge p. 9-10).

Prats teaches precise positioning of a print head in X, Y and Z directions to enhance printing (col. 1, lines 38-55) using an optical positioning system.

It would have been obvious to provide the dispenser of Deeg spaced from the surface in order to permit drop formation and to provide means to move the dispenser relative to the substrate in order to provide art recognized equivalent to moving the substrate relative to the dispenser as taught by Prats. It would have been obvious to provide known alternative position sensing means in the device as modified by Prats as was known in the art. It would have been obvious to provide nucleic acids in order to perform nucleic acid hybridization assays as an alternative specific binding assay as taught by Pirrung.

11. Claims 48, 82, 92, 117, 119, 147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deeg (5378638) in view of Pirrung and Sanz and Meltzer.

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12. Deeg teaches formation of a reagent array using an ink jet printer. Droplets of 20-2000 picoliters are used to make spots of 500 square um to 0.2 square mm and may be bound to the substrate surface (col. 3, lines 27-41). Multiple dispensers may be used (col. 5, lines 35-36). The exemplary reagents are antigens, antibodies and labels used in immunoassay, but other specific binding assays can be used (col. 1, lines 35-43).

Deeg fails to teach nucleic acids or pipets.

Pirrung teaches that nucleic acids may be used in specific binding assays as an alternative to immunoassay (bridge p. 9-10).

Sanz teaches a micropipet for dispensing 1 nl of biological fluids (col. 1, lines 5-12).

Meltzer teaches a positioning device for pipets for pipetting small volumes. The pipets are precisely located in the X-Y-Z dimensions (col. 1, lines 50-60) by a computer using optical, magnetic or other position detectors (col. 8, lines 1-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the pipet of Sanz with the positioning device of Meltzer in the method of Deeg in order to provide the reagents by known means, the known means being dispenser(s) of small volumes precisely into arrays as taught by Sanz and Meltzer. It would have be obvious to provide nucleic acids in order to perform nucleic acid hybridization assays as an alternative specific binding assay as taught by Pirrung.

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13. Applicant's arguments with respect to claims 48-147 filed April 12, 2002 have been considered but are moot in view of the new ground(s) of rejection.

14. With respect to the rejections in the previous office action mailed December 6, 2002:

15. The rejection over Khrapko et al (Chem. Abstract No. 1991:649536) is withdrawn. The full reference has been obtained. While Khrapko et al (DNA Sequence (1991) teaches covering a 1mm dot with 1 ul drops (p. 376, col. 2, lines 3 and 32) and further that spots as small as 25 um can be used (p. 386, line 35), Khrapko et al (EP 0 535 242 A1) teaches 25-100 um dots (p. 4, line 19) covered by 0.5 ul drops (p. 6, line 4). Thus, this combination of references teaches away from using a smaller volume to cover the smaller area.

16. The rejection over Khrapko et al (EP 0 535 242 A1) in view of Sanz is withdrawn. The volume dispensed by Khrapko is two orders of magnitude greater than that of Sanz, and there is no clear evidence of motivation in the art to use the smaller volume to produce arrays as in Khrapko.

17. The rejection over EP 0063810 is withdrawn. The volume dispensed (100 ul , p. 18, line 25) is two orders of magnitude greater than that claimed, and there is no clear evidence of motivation in the art to use the smaller volume to produce arrays as in EP 0063810.

18. Applicant's amendment filed April 12, 2002 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

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See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jan M. Ludlow
Primary Examiner
Art Unit 1743

jml

May 23, 2003